

Applicants acknowledge the objection to the drawings by the Draftsperson as set forth on Form PTO-948. Corrected drawings are attached herewith. Regarding the Information Disclosure Statement, the Examiner alleges that references BL, BM and DJ recite Accession Numbers which could not be located in the National Center for Biotechnology Information (NCBI) database or in the Derwent sequence database. Copies of DJ, BL and BM are enclosed herewith for the Examiner's convenience.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 21, 66, 69 and 71-72 under 35 U.S.C. § 102(b) as anticipated by Bandman *et al.* (U.S. 5,786,148). The Examiner alleges that Bandman *et al.* teach a HPSK protein sequence 88.8% identical to SEQ ID NO: 525 of the instant application. The Examiner further alleges that Bandman *et al.* teach that the protein sequence disclosed therein may be combined with adjuvants, physiological carriers or be used to produce antibodies.

Applicants respectfully traverse this rejection. The presently pending claims are drawn to isolated polypeptides having at least 90% identity to the entirety of SEQ ID NO: 525 and isolated polypeptide having at least 90% identity to a polypeptide comprising amino acids 1-39 of SEQ ID NO: 525; wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as it is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Moreover, the elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). See also MPEP 2131.

Applicants submit that Bandman *et al.* does not anticipate the polypeptides currently claimed by the applicants. More particularly, Bandman *et al.*, while disclosing a sequence having some degree of similarity to SEQ ID NO: 525, does not disclose a sequence having at least 90% identity to the entirety of SEQ ID NO: 525, as currently claimed, much less that the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

Applicants further submit that amino acids 1-39 of SEQ ID NO: 525 are unique to SEQ ID NO: 525, and thus are not contained in the polypeptide disclosed by Bandman *et al.* Consequently, Bandman *et al.* fails to anticipate the subject matter of new claims 73 and 75, drawn to isolated polypeptides comprising amino acid residues 1-39 of SEQ ID NO: 525. Accordingly, in view of the above amendment and remarks, applicants respectfully request reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. § 102(b).

The Examiner also rejects claims 21, 66-69 and 71-72 under 35 U.S.C. § 102(e) as anticipated by Gimeno *et al.* (U.S. 5,955,306). In particular the Examiner alleges that Gimeno *et al.* teach a protein that is 97.6% identical to SEQ ID NO:525 of the instant application. The Examiner further alleges that Gimeno *et al.* teach that immunogenic proteins may be mixed with adjuvants and/or formulated in physiological acceptable carriers.

Applicants respectfully traverse this rejection. As noted above, the currently claimed invention is drawn to isolated polypeptides having at least 90% identity to the entirety of SEQ ID NO: 525; and isolated polypeptides having at least 90% identity to a polypeptide comprising amino acids 1-39 of SEQ ID NO: 525. Applicants submit that Gimeno *et al.*, while describing a sequence having some degree of similarity with the polypeptide of SEQ ID NO: 525, does not specifically describe in complete detail the polypeptides as currently claimed by the applicants, much less that the polypeptides contain an amino acid sequence capable of stimulating human T-cells. Accordingly, the instant claims, as amended hereinabove, are indeed novel over Gimeno *et al.* Reconsideration and withdrawal of the Examiner's rejection are thus respectfully requested.

Rejection under 35 U.S.C. § 103

The Examiner rejects claims 21-22, 66, 69 and 71-72 under 35 U.S.C. § 103(a) as unpatentable over Bandman *et al.* in view of Hauser *et al.* (U.S. 5,776,463), and over Gimeno *et al.* in view of Hauser *et al.* (U.S. 5,776,468). In particular the Examiner alleges that Bandman *et al.* and Gimeno *et al.* teach the polypeptide according to the instant application and that Hauser *et al.* provides an immunostimulant which induces a type I response.

As noted above, neither Bandman *et al.* nor Gimeno *et al.* teach the currently claimed polypeptides related to SEQ ID NO: 525. Moreover, the deficiencies of Bandman *et al.*

and Gimeno *et al.* are not remedied by Houser *et al.*, which merely discloses an immunostimulant, but does not disclose a polypeptide presently claimed by Applicants. Accordingly, Applicants submit that neither Bandman *et al.*, nor Gimeno *et al.*, alone or in combination with Hauser *et al.*, would lead the skilled artisan to any expectation of arriving at the Applicants' claimed invention when the combined disclosures of these references simply do not teach each and every element currently claimed. Applicants respectfully request that this rejection under 35 U.S.C. § 103(a) be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current Amendment, the first page of which is captioned "Version with Markings to Show Changes Made."

Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is invited to contact the undersigned at (206) 694-4885 with any questions, comments and/or suggestions relating to this communication. Please credit any overpayment or charge any deficiency to Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



Jeffrey Hundley, Ph.D., Patent Agent
Registration No. 42,676

JEH:sds

Enclosure:

Postcard

14 Sheets Drawings (Figs. 1-12B)

3 References

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please replace the paragraph on page 1, under the heading "CROSS REFERENCE TO RELATED APPLICATIONS" with the following rewritten paragraph.

--This application is a continuation-in-part of U.S. Patent Application No. 09/443,686, filed November 18, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/352,616, filed July 13, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/288,946, filed April 9, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/232,149, filed January 15, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/159,812, filed September 23, 1998, which is a continuation-in-part of U.S. Patent Application No. 09/115,453, filed July 14, 1998, which is a continuation-in-part of U.S. Patent Application No. 09/030,607, filed February 25, 1998, which is a continuation-in-part of U.S. Patent Application No. 09/020,956, filed February 9, 1998, which is a continuation-in-part of U.S. Patent Application No. 08/904,804, filed August 1, 1997, which is a continuation-in-part of U.S. Patent Application No. 08/806,099, filed February 25, 1997.--

In the Claims:

Claims 66-71 have been canceled, claim 72 has been amended and claims 73-79 are newly added.

72. (Amended) A composition comprising an immunostimulant and an isolated polypeptide having at least 90% identity to the entirety of SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells, according to any one of claims 65-70.

73. (New) A composition comprising an immunostimulant and an isolated polypeptide having at least 90% identity to a polypeptide comprising amino acids 1-39 of SEQ

ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

74. (New) A composition comprising an immunostimulant and an isolated polypeptide comprising SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

75. (New) A composition comprising an immunostimulant and an isolated polypeptide comprising amino acids 1-39 of SEQ ID NO: 525, wherein the polypeptide contains an amino acid sequence capable of stimulating human T-cells.

76. (New) The composition according to claim 72, wherein the polypeptide has at least 95% identity to the entirety of SEQ ID NO: 525.

77. (New) The composition according to any one of claims 72-76, wherein the immunostimulant is selected from the group consisting of a monophosphoryl lipid A, a CpG-containing oligonucleotide, a saponin, or a combination thereof.

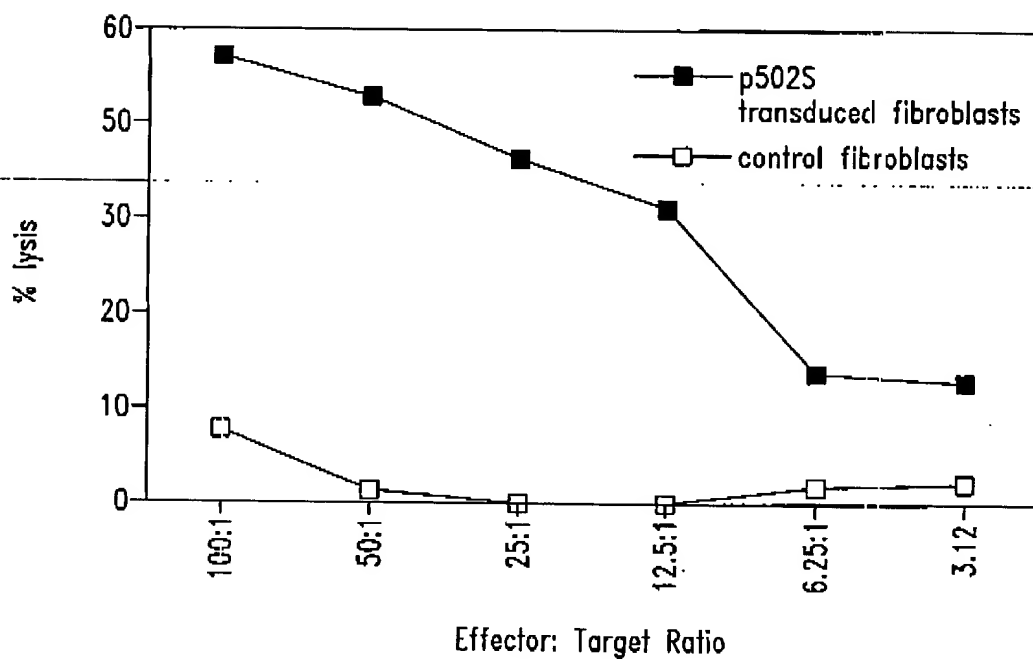
78. (New) The composition according to any one of claims 72-76, wherein the immunostimulant is selected from the group consisting of 3D-MPL, QS21, or a combination thereof.

79. (New) The composition according to any one of claims 72-76, wherein the immunostimulant comprises 3D-MPL, QS21 and tocopherol in an oil-in-water emulsion.

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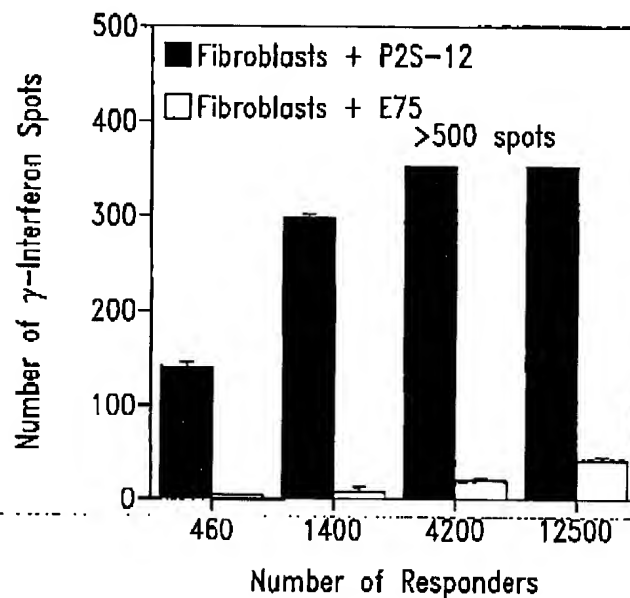
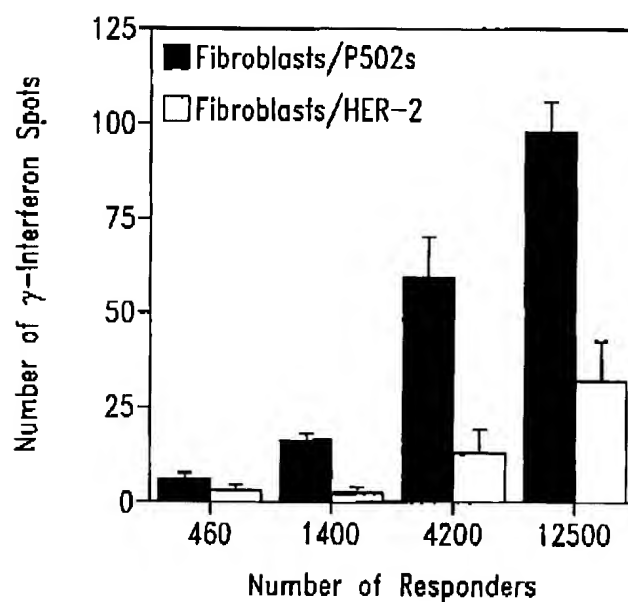
Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

*Fig. 1*

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

*Fig. 2A**Fig. 2B*

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

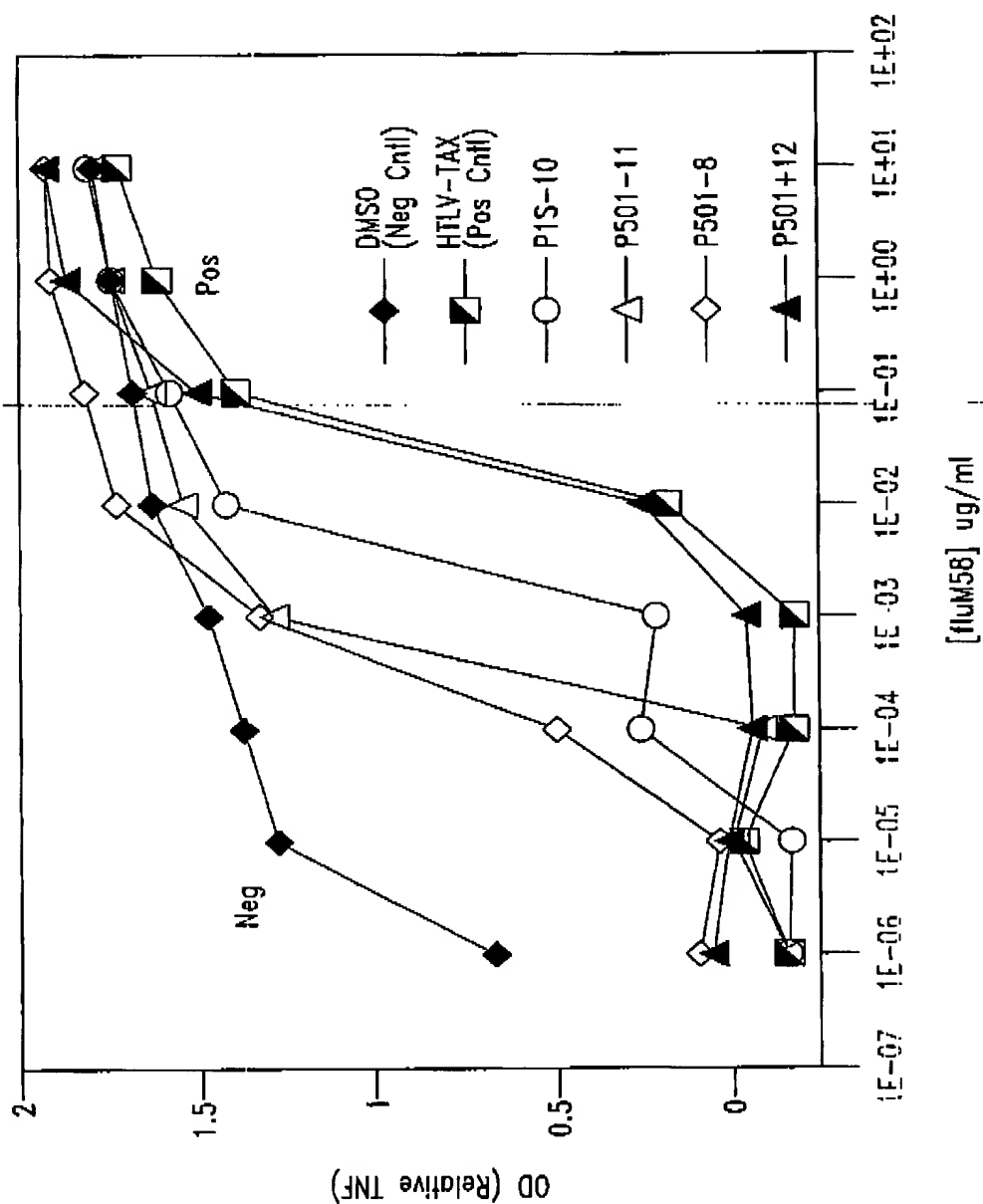
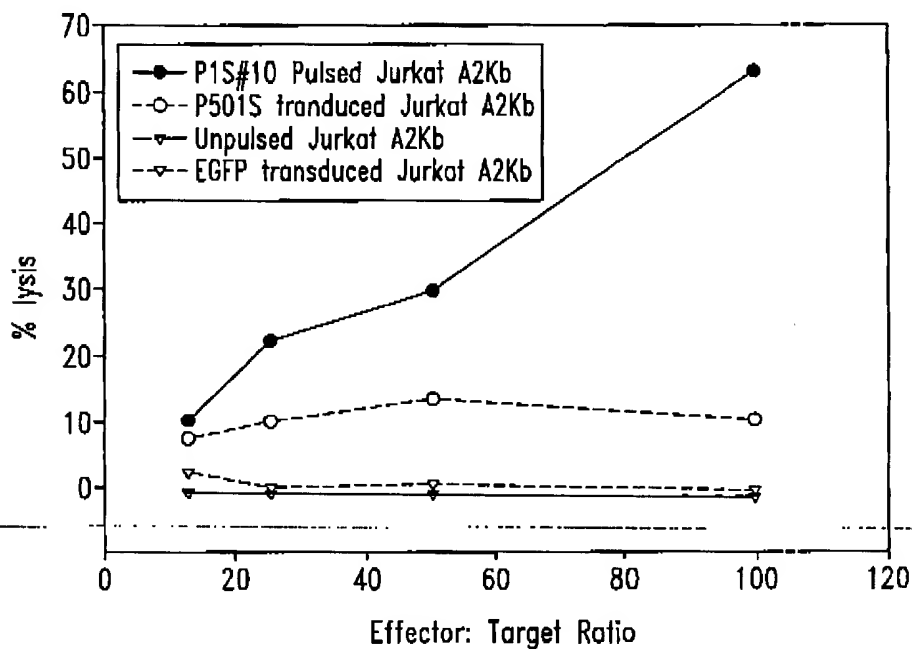
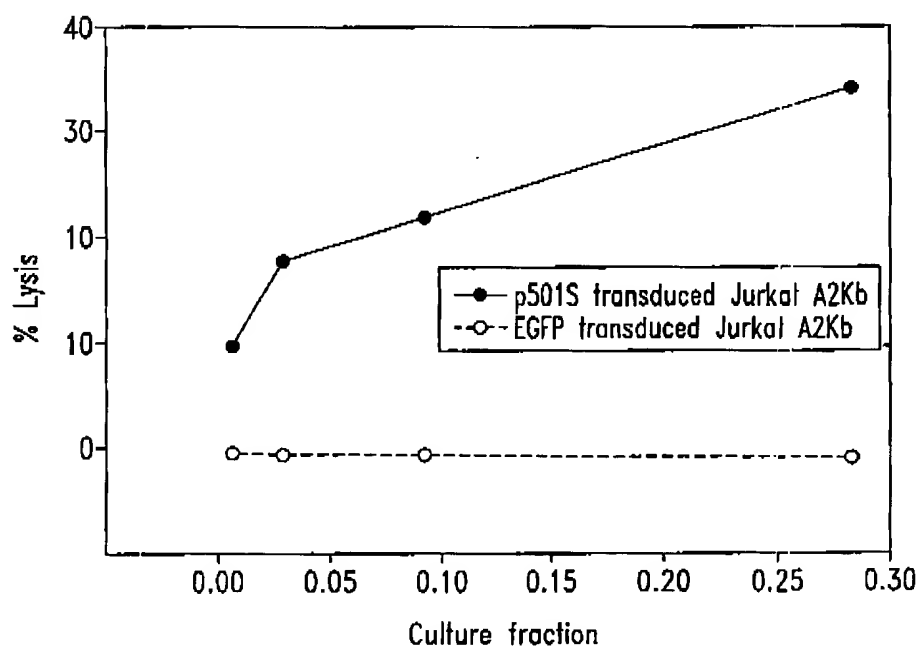


Fig. 3

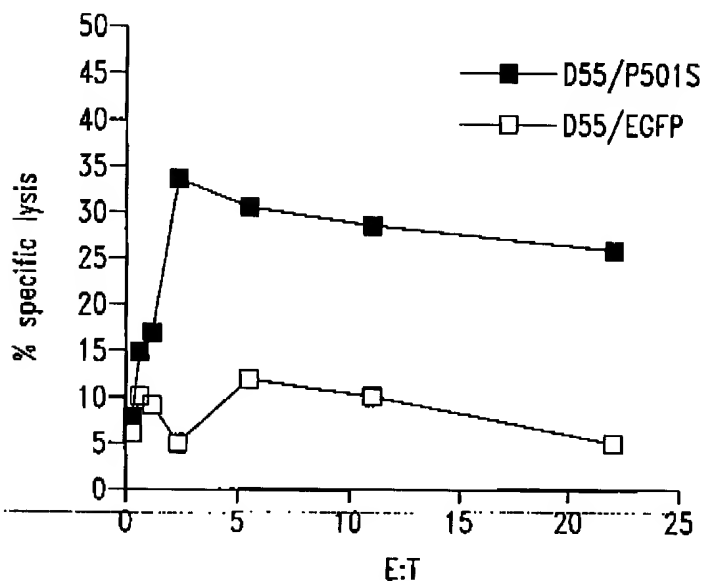
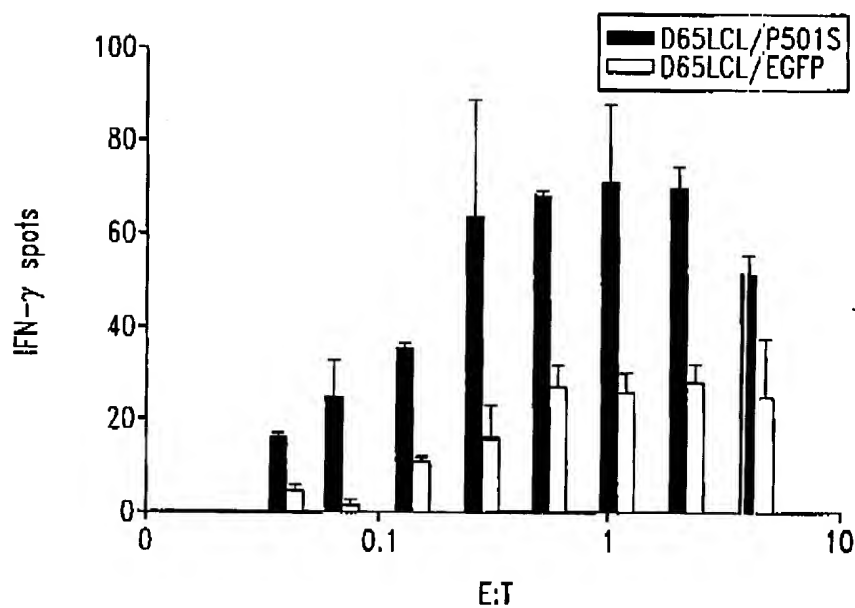
Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

*Fig. 4**Fig. 5*

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

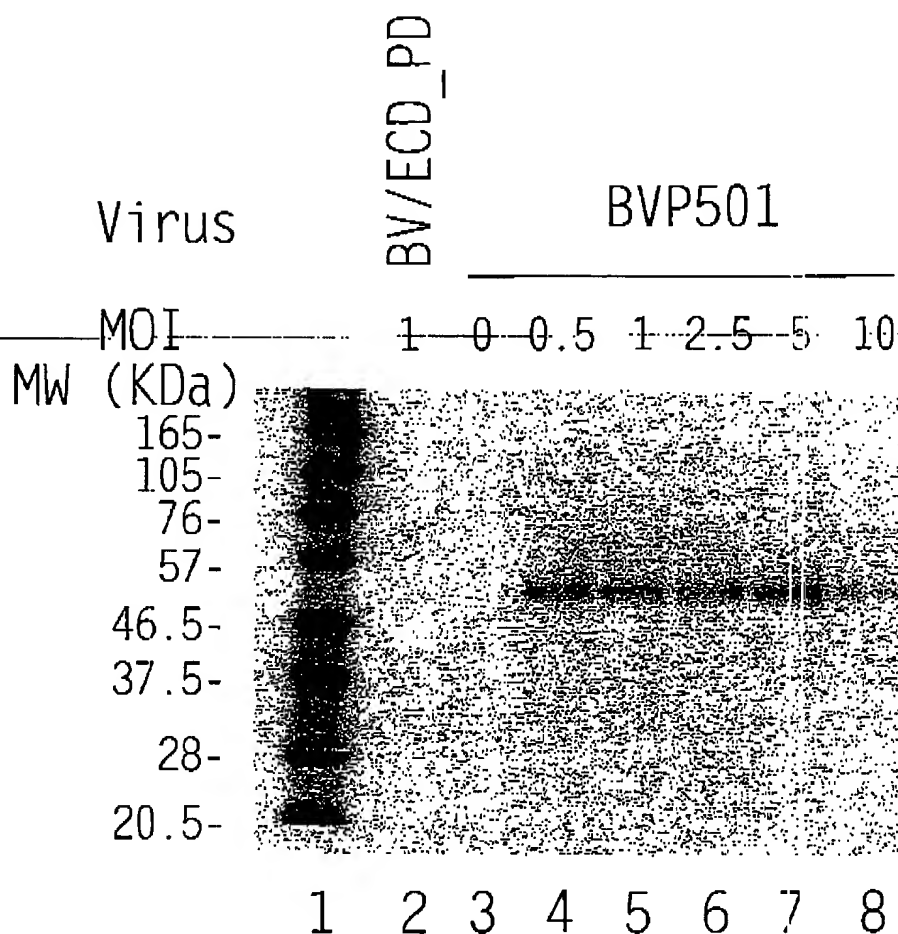
Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

*Fig. 6A**Fig. 6B*

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

Expression of P501S
by the Baculovirus Expression System



C 6 million high 5 cells in 6-well plate were infected with an unrelated control virus BV/ECD_PD (lane2), without virus (lane3), or with recombinant baculovirus for P501 at different MOIs (lane 4-8). Cell lysates were run on SDS-PAGE under the reducing conditions and analyzed by Western blot with a monoclonal antibody against P501S (P501S-10E3-G4D3). Lane 1 is the biotinylated protein molecular weight marker (BioLabs).

Fig. 7

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

FIGURE 8. Mapping of the epitope recognized by 10E3-G4-D3

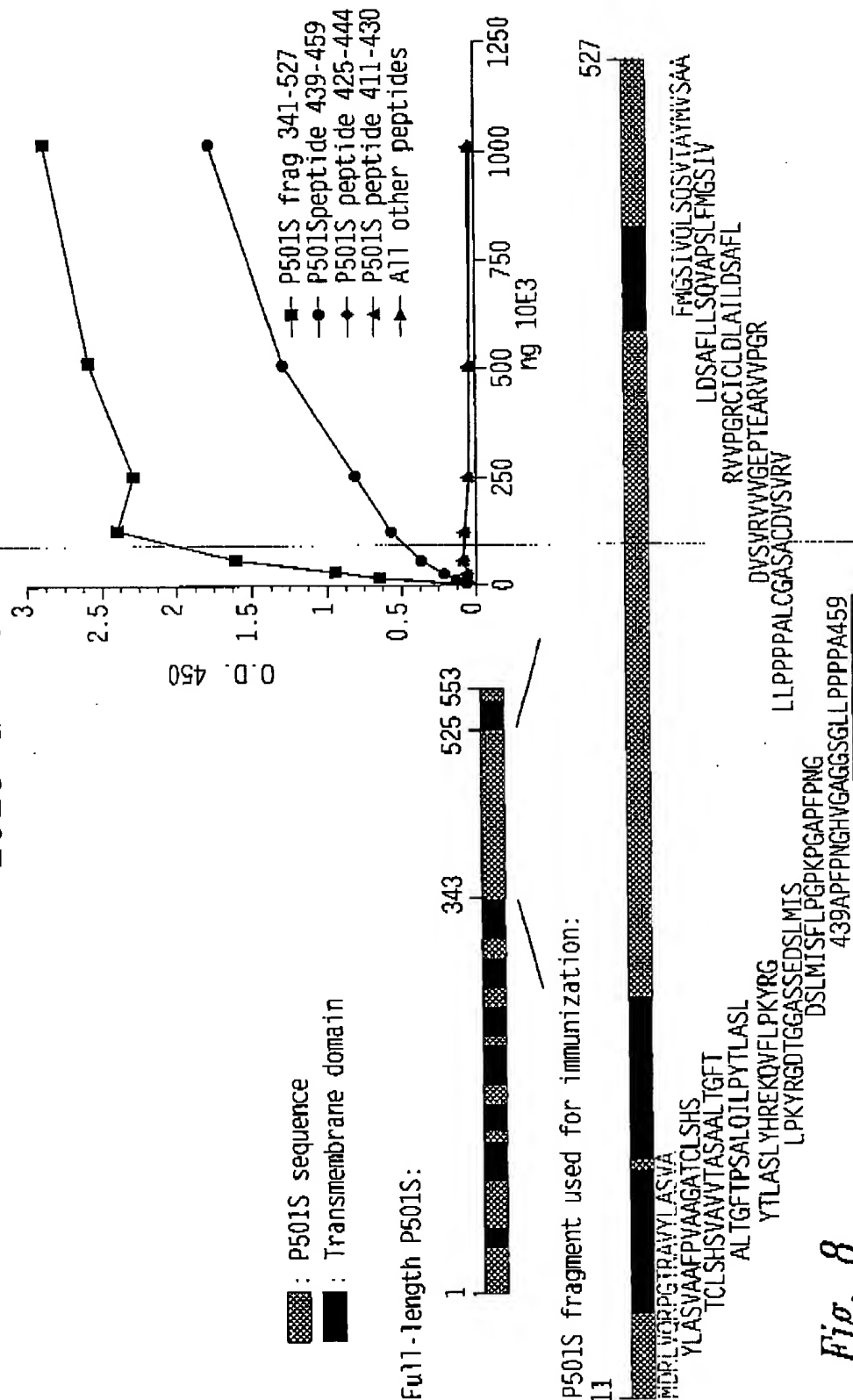


Fig. 8

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

Schematic of P501S with predicted
transmembrane, cytoplasmic, and extracellular regions

MVQRLWVSRLLRHRK AQLLLVNLLTFGLEVCLAAGIT **YVPPLLLLEVGVEEKFM**
TMVLGIGPVLGLVCYPLLGSAS
 DHWRGRYGRRRP FIWALSIGILLSLFLIPRAGWL AGLLCPDPRPLE LALLILGVGLLDFCGQVCFTPL
 EALLSDLFRDPDHCRC AYSVYAFMISLGGCLGYLLPAI **DWDTSALAPYLGTQEE**
CLFGLLTLIFLTCVAATLLV AEAAALGPTEPAEGLSAPSLSPHCCPCRARLAFRNLGALLPRL

HQLCCRMPTLRR LFVAELCSWMALMTFTLFYTDF VGEGLYQGVPRAEPGTEARRHYDEGVR
MGSLGLFLQCAISLVFSLVM DRLVQRFGTRAVYLAS VAAFPVAAGATCLSHSVAVVTA **SAA**
LTGFTFSALQILPYTLASLY HREKQVFLPKYRGDTGGASSED SLMTSFLPGPKPGA **FPNGHVGAGGSGL**
LPPPPALCGASACDVSVRVVVGEPTEARVVVPRG ICDLAILDSAFLLSQVAPSLF **MGSIVQLSQS**
VTAYMVSAAGLGLVAIYFAT QVVFDKSDLAKYSA

Underlined sequence: Predicted transmembrane domain; **Bold** sequence:
 Predicted extracellular domain; *Italic* sequence: Predicted intracellular
 domain. Sequence in bold/underlined: used generate polyclonal rabbit
 serum

Localization of domains predicted using HMMTOP (G.E. Tusnady and I. Simon
 (1998) Principles Governing Amino Acid Composition of Integral Membrane
 Proteins: Applications to topology Prediction. J.Mol Biol. 283. 489-506.

Fig. 9

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

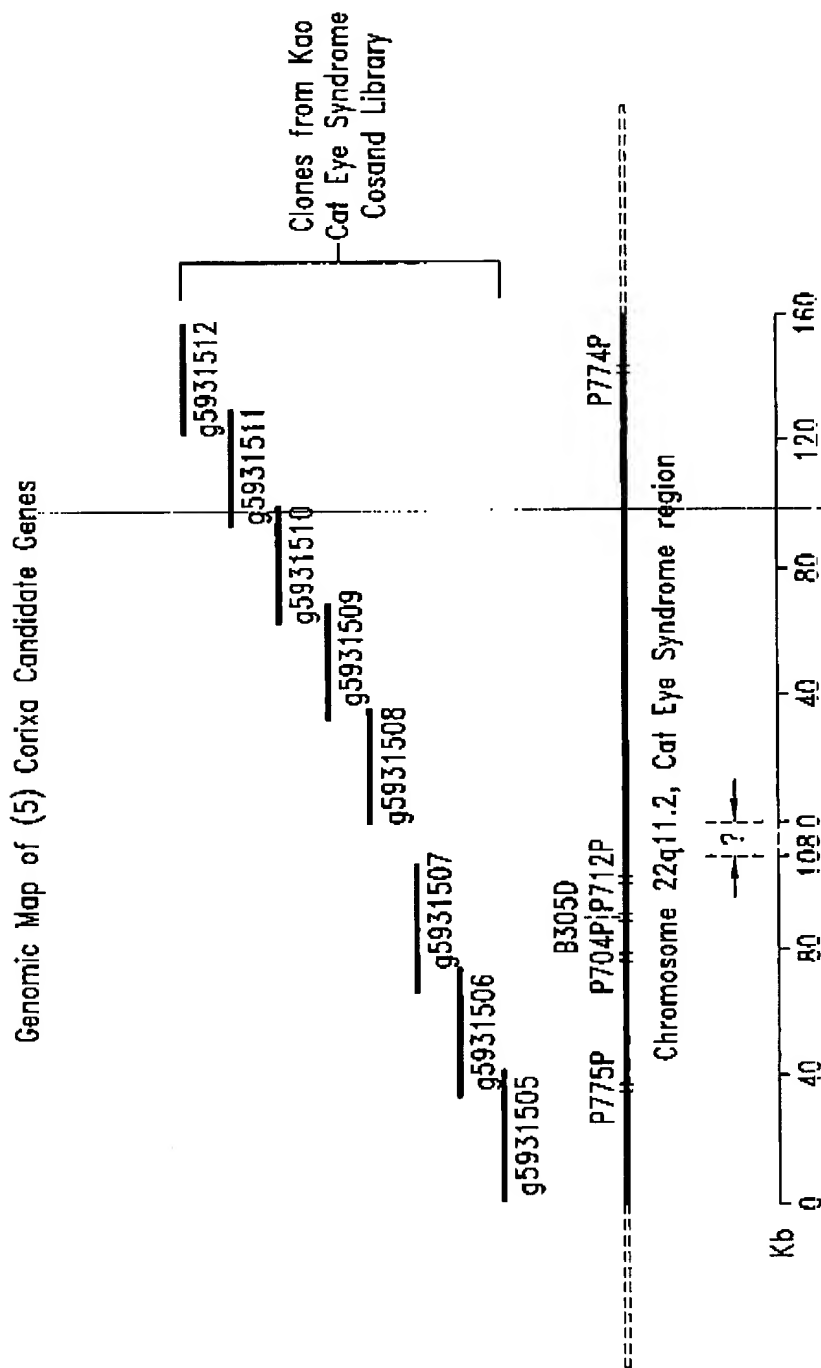


Fig. 10

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

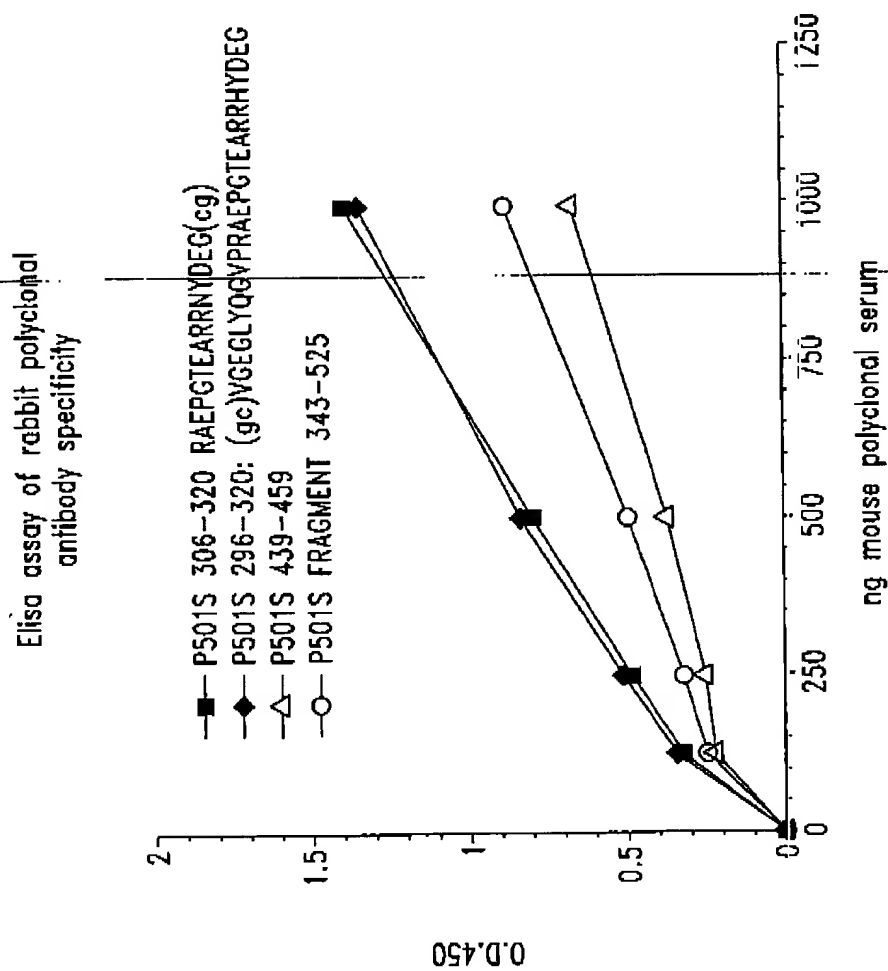


Fig. 11

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

GTCACCTAGG AAAAGGTGTC CTTTCGGGCA GCCGGGCTCA GCATGAGGAA CAGAAGGAAT 60
 GACACTCTGG ACAGCACCCG GACCCTGTAC TCCAGCGCGT CTCGGAGCAC AGACTTGTCT 120
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 AAGTATATAC GTCTGTCTG CGACACGGAC GCGGAAATCC TTTACGAGCT GCTGACCCAG 420
 CACTGGCACC TGAAAACACC CAACCTGGTC ATTTCTGTGA CCGGGGGCGC CAAGAAGCTT 480
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 GCTTGGGGCA TGGTCTCCAA CCGGGACACC CTCATCAGGA ATTGCGATGC TGAGGGCTAT 720
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 AACCACACAC ATTTGCTGCT CGTGGACAAT GGCTGTCATG GACATCCAC TGTCGAAGCA 840
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~~GCTGGCAAGA TCCCCATTGT GTGTTTGGC CAAGGAGGTG GAAAAGAGAC FTTGAAAGCC 960~~
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Fig. 12A (1)

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

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Fig. 12A (2)

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

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Fig. 12A (3)

Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF PROSTATE CANCER

Inventor(s): Jiangchun Xu et al. Serial No. 09/483,672 Docket No. 210121.427C11

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Fig. 12B

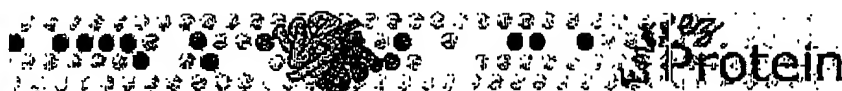
L3 ANSWER 1 OF 1 DGENE COPYRIGHT 2001 DERWENT INFORMATION LTD
 AN AAV58522 cDNA DGENE
 TI Novel human prostate specific tumour protein and fragments - useful for
 detecting and treating prostate cancers
 IN Dillon D C; Xu J
 PA (CORI-N) CORIXA CORP.
 PI WO 9837418 A2 19980827 141p
 AI WO 1998-US3690 19980225
 PRAI US 1998-904809 19980209
 US 1997-806596 19970225
 US 1997-904809 19970801
 PSL Claim 1; Page 56
 DED 08 DEC 1998 (first entry)
 DT Patent
 LA English
 OS 1998-480805 [41]
 DESC Prostate tumour specific gene clone P20.
 KW Prostate tumour specific gene; human; prostate cancer; detection;
 therapy; ss.
 ORGN Homo sapiens.
 AB This sequence represents a human prostate tumour specific gene, and can
 be used in the method of the invention. The method is for detecting
 prostate cancer comprises contacting a biological sample with an agent
 able to bind an immunogenic portion of a prostate protein (such as
 encoded by this sequence). An antibody which binds to an immunogenic
 portion of the prostate protein, and the method can be used to detect,
 monitor progression of, or treat prostate cancers. The antibody may also
 be conjugated to a therapeutic agent for use in therapy of prostate
 cancers.
 NA 43 A; 68 C; 68 G; 55 T; 0 other
 SQL 234
 SEQ
 1 acaacagacc cttgctcgct aacgacctca tgctcatcaa gttggacgaa
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L4 ANSWER 1 OF 1 DGENE COPYRIGHT 2001 DERWENT INFORMATION LTD
 AN AAV61287 cDNA DGENE
 TI Polypeptides comprising immunogenic portions of prostate proteins - used
 in a vaccine for the treatment of prostate cancer
 IN Dillon D C; Xu J
 PA (CORI-N) CORIXA CORP.
 PI WO 9837093 A2 19980827 130p
 AI WO 1998-US3492 19980225
 PRAI US 1998-20956 19980209
 US 1997-806099 19970225
 US 1997-904804 19970801
 PSL Claim 12; Page 61
 DED 06 JAN 1999 (first entry)
 DT Patent
 LA English
 OS 1998-609886 [51]
 DESC cDNA sequence of prostate tumour clone P80.
 KW Prostate; cancer; tumour; vaccine; immunogen; clone; ss.
 ORGN Homo sapiens.
 AB The present sequence is a DNA which encodes an immunogenic portion of a
 prostate tumour protein. The encoded immunogen, or the DNA itself, can be
 used as a vaccine for the treatment of prostate cancer. The DNA was
 identified by analysis of a subtracted cDNA library obtained by
 subtracting a prostate tumour cDNA expression library with a normal
 tissue cDNA library.

NA 86 A; 105 C; 94 G; 100 T; 0 other
 SQL 385
 SEQ

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LOCUS NP_004908 254 aa PRI 18-MAR-2000
 DEFINITION kallikrein 4 (prostase, enamel matrix, prostate) [Homo sapiens].
 ACCESSION NP_004908
 PID g4758960
 VERSION NP_004908.1 GI:4758960
 DBSOURCE REFSEQ: accession NM_004917.1
 KEYWORDS
 SOURCE human.
 ORGANISM Homo sapiens
 Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
 Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.

REFERENCE 1 (residues 1 to 254)
 AUTHORS Nelson PS, Gan L, Ferguson C, Moss P, Gelinas R, Hood L and Wang K.
 TITLE Molecular cloning and characterization of prostase, an androgen-regulated serine protease with prostate-restricted expression
 JOURNAL Proc. Natl. Acad. Sci. U.S.A. 96 (6), 3114-3119 (1999)
 MEDLINE 99179024
 PUBMED 10077646

REFERENCE 2 (residues 1 to 254)
 AUTHORS Stephenson SA, Verity K, Ashworth LK and Clements JA.
 TITLE Localization of a new prostate-specific antigen-related serine protease gene, KLK4, is evidence for an expanded human kallikrein gene family cluster on chromosome 19q13.3-13.4
 JOURNAL J. Biol. Chem. 274 (33), 23210-23214 (1999)
 MEDLINE 99367447
 PUBMED 10438493

REFERENCE 3 (residues 1 to 254)
 AUTHORS Yousef GM, Obiezu CV, Luo LY, Black MH and Diamandis EP.
 TITLE Prostase/KLK-L1 is a new member of the human kallikrein gene family, is expressed in prostate and breast tissues, and is hormonally regulated
 JOURNAL Cancer Res. 59 (17), 4252-4256 (1999)
 MEDLINE 99413477
 PUBMED 10485467

REFERENCE 4 (residues 1 to 254)
 AUTHORS DuPont BR, Hu CC, Reveles X and Simmer JP.
 TITLE Assignment of serine protease 17 (PRSS17) to human chromosome bands 19q13.3-->q13.4 by in situ hybridization
 JOURNAL Cytogenet. Cell Genet. 86 (3-4), 212-213 (1999)
 MEDLINE 20044607
 PUBMED 10575207

COMMENT REFSEQ: The reference sequence was derived from AF013141.1.
 PROVISIONAL RefSeq: This is a provisional reference sequence record that has not yet been subject to human review. The final curated reference sequence record may be somewhat different from this one.
 Method: conceptual translation.

FEATURES
 source Location/Qualifiers
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CBI Sequence Viewer

Page 2 of 2

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         /coded_by="NM_004917.1:1..765"
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121 kldevsesd tirsisiast cptagnsclv sgwgllangr mptvlqcnv svvseevcsk
181 lydplyhpsm fcaggghdqk dscngdsggp licngylqgl vsfgkapcgq vgvpgvytnl
241 ckftewiekt vqas
//
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